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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

LORI CARTER and MARK CARTER, *wife and husband and their marital community comprised thereof,* *Plaintiffs*, v. JOHNSON AND JOHNSON; ETHICON, INC. *Defendants*.	Case No. **COMPLAINT** ***JURY TRIAL DEMANDED***

I. CIVIL ACTION COMPLAINT

Plaintiffs LORI CARTER and MARK CARTER ("Plaintiffs"), by and through their counsel, bring this Complaint against Defendants ETHICON, INC., and JOHNSON & JOHNSON (collectively, "Defendants", as the context may require) for injuries suffered as a result of defective pelvic mesh products designed, manufactured and marketed by Defendants, and implanted in Plaintiff LORI CARTER. In support, Plaintiffs state and aver as follows:

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II. PARTIES

1. Plaintiffs LORI CARTER and MARK CARTER are, and were, at all relevant times, residents of the State of Washington.

2. Defendant, Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson and is located in Somerville, New Jersey.

3. Defendant Johnson & Johnson is a corporation, and according to its website, the world's largest and most diverse medical devices and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

4. Defendants ETHICON, INC. and JOHNSON & JOHNSON share many of the same officers, directors and operations; and maintain ownership in the assets and/or liabilities relating to the design, manufacture, marketing, distribution and sale of the medical device line at issue in this litigation and shall be referenced collectively hereinafter as "Defendants".

5. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

III. JURISDICTION AND VENUE

6. Damages sought in this matter are in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

7. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

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8. Venue is proper in the Western District Court of Washington pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in this district.

9. Defendants conducted substantial business in the State of Washington and in this District, distribute Pelvic Mesh Products in this District, receive substantial compensation and profits from sales of Pelvic Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District.

10. Defendants conducted business in the State of Washington through sales representatives and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promotion and/or selling, either directly or indirectly, and/or through third parties or related entities, Pelvic Mesh Products in the State of Washington; thus, there exists a sufficient nexus between Defendants forum contacts and the Plaintiffs' claims to justify assertion of jurisdiction in Washington.

11. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Washington such that requiring an appearance does not offend traditional notices of fair play and substantial justice.

IV. DEFENDANTS' PELVIC MESH PRODUCTS

12. In or about October, 2002, the Defendants began to market and sell a product known as Gynemesh, for the treatment of medical conditions in the female pelvis, primarily

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pelvic organ prolapse and stress urinary incontinence. All references to Gynemesh include all variations of or names used for Gynemesh, including but not limited to Gynemesh PS.

13. Gynemesh was derived from a product known as Prolene Mesh, which was used in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. Prolene Mesh was derived from Defendants' prolene mesh hernia product, and was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Prolene Mesh include all variations of Prolene Mesh, including but not limited to Prolene Soft Mesh.

14. In or about September, 2005, the Defendants began to market and sell a product known as Prolift, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift include by reference all variations.

15. In or about May, 2008, the Defendants began to market and sell a product known as Prolift+M, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift+M was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift+M include by reference all variations.

16. The Defendants market and sell a product known as TVT, for the treatment of stress urinary incontinence in females. The TVT has been and is offered in multiple variations including, but not limited to, the TVT, TVT-O, and TVT-S, and all references to the TVT include

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by reference all variations.

17. The products known as Prolene Mesh, Gynemesh,, Prolift, Prolift+M, and TVT, as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Defendants' Pelvic Mesh Products or the Pelvic Mesh Products.

18. Defendants' Pelvic Mesh Products were designed, patented, manufactured, labeled, marketed, and sold and distributed by the Defendants, at all times relevant herein.

V. FACTUAL BACKGROUND

19. In or before February, 2010, Plaintiff LORI CARTER was diagnosed with stress urinary incontinence.

20. On February 12, 2010, Plaintiff LORI CARTER underwent surgery to correct her symptoms at Good Samaritan Hospital in Puyallup, Washington.

21. The medical device used in Plaintiff's surgery was the J&J Gynecare TVT-O sling, which was designed, manufactured, and sold by Defendants.

22. Plaintiff's surgery was performed without complications. She was discharged the day of surgery.

23. Plaintiff suffered from endometriosis, and on August 14, 2014 she underwent a vaginal hysterectomy; bilateral salpingooophorectomy and placement of AMS Monarc Suburethral Sling at Tacoma General Hospital in Tacoma, Washington.

24. Plaintiff's surgery was performed without complications. She was discharged the day following the surgery.

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25. On December 5, 2014 Plaintiff presented at Virginia Mason Medical Center, in Seattle, Washington, with vaginal mass, vaginal pain. Plaintiff underwent the following procedure: excision and removal of vaginal mass, and over-sew of vaginal cuff defect with electrocautery of granulation tissue site.

26. On July 24, 2015 Plaintiff underwent a Robotic obturator exploration with removal of sling material and cystoscopy to treat the ongoing pelvic pain with obturator muscle spasm after placement of transobturator sling.

27. On December 22, 2015, Plaintiff underwent urethral bulking with macroplastique at Athena Women's Health in Issaquah, Washington.

28. Plaintiff continued to have pelvic pain. On May 12, 2016 Plaintiff underwent urethrolysis, suburethral sling removal, right paravaginal defect repair at Swedish Medical Center, in Seattle, Washington.

29. On October 14, 2016; October 28, 2016; November 5, 2016; January 27, 2017; and June 9, 2017, Plaintiff underwent pudendal nerve blocks with Dr. Jason Attaman, in Seattle, Washington.

30. On December 15, 2017, Plaintiff underwent robotic sacral colpopexy, paravaginal repair, pudendal nerve block and placement of retropubic sling to treat her 3rd degree cystocele and 90 degree rotation of her urethra.

31. Currently Plaintiff cannot sit for more than 15 minutes without having to adjust due to the pain. MARK CARTER has taken on all the household chores because LORI CARTER cannot do them anymore. She is unable to grocery shop or walk more than a half

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mile. Plaintiff continues to suffer from pain in her vagina and groin and has a constant need to lie down, all the while adjusting and changing positions

32. The severe problems that Plaintiff suffered after her implant surgery were caused by the not reasonably safe design and manufacture of the Medical Device that was surgically implanted in her. In addition, the revision surgeries that Plaintiff underwent were necessitated by the not reasonably safe design and manufacture of the Medical Device used in the Plaintiff's original procedure.

33. Plaintiff is not alone in sustaining injury as a result of the not reasonably safe design and manufacture of Defendants' Medical Device. The FDA has received thousands of reports of women who were injured or killed after being implanted with devices similar to that used in Plaintiff's original implant procedure.

34. As discussed below, the FDA responded to the volume of reports of injuries arising from the implant of surgical mesh by issuing a "Public Health Notification" relating to the use of these devices. In July 2011, the FDA also took the unusual step of issuing an "update" to this Public Health Notification. In 2019 the FDA banned the further sale of transvaginal mesh slings for pelvic organ prolapse. These publications confirm the dangerous nature of the Defendants' mesh products, including the Gynecare TVT-O sling used in Plaintiff's surgery.

35. As a result of having the Product implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury and permanent and substantial physical deformity and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

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36. The Defendants have marketed and sold their Pelvic Mesh Product to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable consideration and benefits to health care providers. Also utilized are documents, brochures, websites, and telephone information lines, offering exaggerated and misleading expectations as to the safety and utility of the Defendants' Pelvic Mesh Product.

37. Contrary to the Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Pelvic Mesh Product has high failure, injury, and complication rates, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff.

38. The Defendants have consistently underreported and withheld information about the propensity of Defendants' Pelvic Mesh Product to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Product, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

39. Defendants have known and continue to know that their disclosures to the FDA were and are incomplete and misleading; and that the Defendants' Pelvic Mesh Product was and is causing numerous patients' severe injuries and complications. The Defendants suppressed this

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information and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Defendants' Pelvic Mesh Product was and is safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Product into the Plaintiff.

40. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants' Pelvic Mesh Product.

41. Defendants failed to design and establish a safe, effective procedure for removal of the Defendants' Pelvic Mesh Product; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendants' Pelvic Mesh Product.

42. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and similar other conditions have existed at all times relevant as compared to the Defendants' Pelvic Mesh Product.

43. The Defendants' Pelvic Mesh Product was at all times utilized and implanted in a manner foreseeable to the Defendants.

44. The Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' Pelvic Mesh Product, and thus increase the sales of the Product, and also leading to the dissemination of inadequate and misleading information to patients, including

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Plaintiff.

45. The Pelvic Mesh Product implanted into the Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants, and in the condition directed by and expected by the Defendants.

46. The injuries, conditions, and complications suffered due to Defendants' Pelvic Mesh Product include but are not limited to mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to Plaintiff's intimate partners.

47. Despite Defendants' knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Product, the Defendants have, and continue to manufacture, market, and sell the Product, while continuing to fail to adequately warn, label, instruct, and disseminate information with regard to the Defendants' Pelvic Mesh Product, both prior to and after the marketing and sale of the Product.

VI. FIRST CAUSE OF ACTION
WASHINGTON PRODUCT LIABILITY ACT

48. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if

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fully set forth herein and further alleges as follows:

49. At all times relevant to this litigation, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting its medical device products.

50. At all times relevant to this litigation, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, and distributed the medical device used by Plaintiff as described above.

51. At all times relevant to this litigation, Defendants' medical device was expected to reach and did reach the intended consumers, handlers, and users or other persons coming into contact with these products in Washington and throughout the United States, including Plaintiffs, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

52. In violation of the Washington Products Liability Act ("WPLA"), RCW 7.72, et seq., at all times relevant to this action, at the time Defendants' medical device left control of Defendants, it was defective and not reasonably safe. These defects include, but are not limited to, the following:

a) Defendants are strictly liable for Plaintiff's injuries and damages because at the time of manufacture, and at the time Defendants' medical device left control of Defendants, the likelihood that the medical device would cause injury or damage similar to that suffered by Plaintiff, and the seriousness of such injury or damage had been known by Defendants and outweighed the burden on Defendants to design a product that would have prevented Plaintiff's injuries and damages and outweighed the adverse effect that an alternative design that was practical and feasible would have on the usefulness of the subject product.

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b) Defendants' medical device is unsafe to an extent beyond that which would be contemplated by an ordinary consumer.

c) The medical device manufactured and/or supplied by Defendants was defective in design in that, an alternative design and/or formulation exists that would prevent severe and permanent injury. Indeed, at the time that Defendants designed their medical device, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable.

d) The medical device was not reasonably safe in design under the WPLA.

e) The medical device manufactured and/or supplied by Defendants was not reasonably safe because Defendants did not provide an adequate warning or instruction about the product. At the time the medical device left Defendants' control, the device possessed dangerous characteristics and Defendants failed to use reasonable care to provide an adequate warning of such characteristics and their danger to users and handlers of the product. The medical device is not safe and cause severe and permanent injuries. The medical device was not reasonably safe because the warning was inadequate, and Defendants could have provided adequate warnings or instructions.

f) The medical device that was manufactured and/or supplied by Defendants was not reasonably safe because adequate warnings or manufacturer instructions were not provided after the medical device was manufactured and when Defendants learned of, or should have learned of, the dangers connected with the medical device.

g) The medical device manufactured and/or supplied by Defendants was not reasonably safe because it did not conform to an express warranty made by Defendants regarding the product's safety and fitness for use. Defendants expressly warranted that the medical device was safe and fit for their intended purposes, that it was of merchantable quality, that it was not produce any dangerous side effects, that they were adequately tested, and that the device was safe to human health and the environment, and effective, fit, and proper for its intended use. Defendants did not disclose the material risks that its medical device could cause severe and permanent injury. Defendants' express

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warranty induced Plaintiff to use the device, and Plaintiff's damages were proximately caused because Defendants' express warranty was untrue. The mesh product was not reasonably safe because of nonconformity to express warranty under the WPLA.

53. As a direct and proximate result of Defendants placing their defective medical device into the stream of commerce, Plaintiff LORI CARTER has suffered grave injuries, and endured physical and emotional pain and discomfort, as well as economic hardship, including considerable financial expenses for medical care and treatment and other damages further discussed in herein, and MARK CARTER has suffered loss of consortium.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

VII. SECOND CAUSE OF ACTION
VIOLATION OF THE WASHINGTON CONSUMER PROTECTION ACT

54. Plaintiffs reallege and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

55. Plaintiff LORI CARTER purchased and used the Defendants' Pelvic Mesh Product primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

56. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' Pelvic Mesh Product and would not have incurred related medical costs and injury.

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57. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Pelvic Mesh Product that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

a) Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

b) Representing that goods or services has characteristics, ingredients, uses benefits or quantities that they do not have;

c) Advertising goods or services with the intent not to sell them as advertised; and,

d) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

58. Plaintiffs' were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' Pelvic Mesh Product. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Pelvic Mesh Product.

59. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Pelvic Mesh Product.

60. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Product and would not have incurred related medical costs.

61. Defendants' deceptive, unconscionable, or fraudulent representations and

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material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

62. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

63. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations.

64. Under applicable state statutes enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

65. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' Pelvic Mesh Product was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

66. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers such as LORI CARTER against unfair, deceptive, fraudulent and unconscionable trade and business practices

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and false advertising.

67. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Pelvic Mesh Product and failed to take any action to cure such defective and dangerous conditions.

68. Plaintiff LORI CARTER and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

69. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

70. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

71. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiffs have sustained economic losses and other damages and is entitled to statutory and compensatory, damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

VIII. LOSS OF CONSORTIUM

72. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if

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fully set forth herein, and further allege:

73. Plaintiff MARK CARTER, at all times relevant, was and is the lawful husband of Plaintiff LORI CARTER.

74. As a direct, legal, and proximate result of the culpability and fault of Defendants, Plaintiff MARK CARTER suffered the loss of support, services, love, companionship, affection, society, intimate relations, and other elements of consortium, all to his general damage in an amount in excess of the jurisdictional minimum of this Court.

75. Plaintiffs demand judgment against Defendants for compensatory and punitive damages such as a jury may award, and such other relief as the Court deems just and proper in order to remedy Plaintiff MARK CARTER's loss of consortium.

IX. PUNITIVE DAMAGES

76. Plaintiffs reallege and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

77. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs for which the law would allow, and which Plaintiffs will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but

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nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs.

78. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

79. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

80. Plaintiffs also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest,

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cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A. All general, statutory, and compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiffs for all general damages, both past and future;
B. All special and economic damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiffs for all of their injuries and damages, past and future;
C. Attorneys' fees, expenses, and costs of this action;
D. Double or triple damages as allowed by law;
E. Punitive and/or exemplary damages;
F. Pre-judgment and post-judgment interest in the maximum amount allowed by land; and
G. Such further relief as this Court deems necessary, just, and proper.

XI. DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues so triable.

Dated this 9th day of July, 2020.

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